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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,001	02/05/2004	Michelle Lu	.680.0045USX	5377
7590	03/30/2005		EXAMINER	
CHARLES N.J. RUGGIERO, ESQ. OHLANDT, GREELEY, RUGGIERO & PERLE, L.L.P. ONE LANDMARK SQUARE, 10th FLOOR STAMFORD, CT 06901-2682			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/773,001	LU ET AL.	
	<b>Examiner</b> Susan D. Coe	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 February 2005.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 1-10, 14 and 17-30 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11-13 and 15 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

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**DETAILED ACTION**

1. The amendment filed February 25, 2005 has been received and entered.
2. Claims 1-30 are currently pending.

***Election/Restrictions***

3. Applicant's election of Group II, claims 11-16, *Salvia miltorrhiza* for species A and prevention and/or reduction in appearance and/or depth of lines and/or wrinkles for species B in the reply filed on February 25, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 1-10, 14, and 17-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 25, 2005.
5. Claims 11-13, 15, and 16 are examined on the merits solely in regards to the elected species.

***Claim Objections***

6. Claim 15 is objected to as being dependent on non-elected claim 1. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1654

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12, 13, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reduction in wrinkles, does not reasonably provide enablement for prevention of wrinkles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a cosmetic that is able to prevent skin wrinkles. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent skin wrinkles for all potential causes of skin wrinkles. In addition, skin wrinkles are known to occur naturally with age despite topical cosmetic use. Thus, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of skin wrinkles.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 11 does not state a transitional phrase for the composition itself; thus, it is unclear if the composition is intended to be open to additional active ingredients. For the sake of examination, the composition will be examined as open.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11-13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Pat. Pub. No. 06-100412, Japanese Pat. Pub. No. 61-271210, US Pat. No. 5,972,341, and US Pat. No. 5,968,423.

JP '412 teaches that a cosmetic containing neem seed (*Azadirachta indica*) increases skin tone (see abstract and paragraphs 27 and 28 of the English abstract).

JP '210 teaches that *Salvia miltiorrhiza* increases skin tone (see English abstract).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in cosmetic compositions that increase skin tone. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior

art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in cosmetic compositions to increase skin tone, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to increase skin tone. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

Thus, the combination of JP '210 and JP '412 is considered to teach a composition comprising neem seed extract and *S. miltiorrhiza* extract to increase skin tone. However, the references do not specifically teach using this composition to decrease skin wrinkles. US '341 teaches that it was known in the art at the time of the invention that cosmetic compositions that increase skin tone reduce the depth of line and wrinkles and make them less obvious (see column 5, lines 35-37). Therefore, a person of ordinary skill in the art would reasonably expect that a skin toning composition comprising neem seed extract and *S. miltiorrhiza* extract would also be useful in reducing the appearance of lines and wrinkles. Based on this reasonable expectation of

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success, a person of ordinary skill in the art would be motivated to use a composition comprising neem seed extract and *S. miltiorrhiza* extract to reduce the appearance of lines and wrinkles.

Thus, taken together, US ‘341, ‘JP ‘210 and JP ‘412 teach using neem seed extract and *S. miltiorrhiza* to reduce the appearance of lines and wrinkles. However, the references do not teach using neem seed cell broth. US ‘423 teaches using cell cultures of neem seed to culture active substances from the neem seed. The reference teaches that the cell culture is advantageous because it increases the availability of neem seed products and reduces potential contaminants (see column 4). Based on this disclosure of advantageous result from neem seed cell cultures, a person of ordinary skill in the art would be motivated to use cell culture to create the neem seed extract taught by JP ‘412.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 11-13, 15 and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-18 of copending

Application No. 10/040242 or claim 13-18 of Application No. 10/845,603 in view of CN

109752.

Appl. '242 and Appl. '603 teaches using neem seed cell to reduce wrinkles. The applicants do not teach using *S. miltiorrhiza*. CN '752 teaches using *S. miltiorrhiza* to treat wrinkles.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in cosmetic compositions to treat wrinkles. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in cosmetic compositions to treat wrinkles, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat wrinkles. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

This is a provisional obviousness-type double patenting rejection.

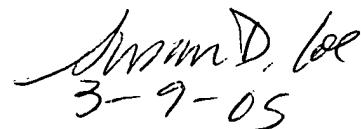
11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



3-9-05

Susan D. Coe  
Primary Examiner  
Art Unit 1654